

REMARKS

Status of Claims

Claims 1, 4-25, 27-29 and 31-33 are pending. The Examiner has withdrawn claims 7-25 and 27-28 from consideration as being directed to non-elected inventions. Claims 1, 4-6, 29, and 33 are amended herein. Support for claims 1 and 29 can be found throughout the specification as filed. *See e.g.*, page 2, line 25- page 7, line 2; Tables 1 and 3. Claims 4 and 5 have been amended to be consistent with the antecedent claim. Support for claims 6 and 33 can be found throughout the specification as filed. *See e.g.*, page 2, line 25- page 7, line 2; page 22, lines 12-18; Tables 1 and 3.

Compliance with Sequence Rules

The Examiner maintained the objection to the specification based on non-compliance with Sequence Rules for Table 2. *See* Final Office Action at 3. In the previous response, Applicants appropriately amended the specification to indicate that Table 2 contains “SEQ ID NOs 4-20, respectively, in order of appearance.” Reply to Office Action dated December 19, 2007. The Examiner states, “[h]owever Table 2 contains only 17 polypeptides.” Final Office Action at 3. Applicants respectfully submit that Table 2 contains SEQ ID NOs 4 to 20 from top to bottom, and that SEQ ID NOs 4 to 20 submitted in the Sequence Listing of December 19, 2007, match the 17 polypeptides in Table 2.

The Examiner alleges that “[t]he previous non-compliance with Sequence Rules for the polypeptide in page 35, line 16 does not have appropriate SEQ ID NO.” *Id.* at 3. Applicants respectfully point to the previous reply wherein the appropriate SEQ ID NO, i.e. SEQ ID NO 3, was added to page 35, line 16. *See* Reply to Office Action dated December 19, 2007, pages 2-3.

Objections to the Specification

The Examiner objects to the specification “because the Table 2 has many gray areas wherein amino acid(s) cannot be deciphered.” Final Office Action at 3. Applicants have revised the table and replaced the areas of gray shading with boxes so that the amino acids can be clearly deciphered. No new matter was added by this formatting change.

Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 6 and 33 under 35 U.S.C. § 112, Second Paragraph, for being “indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.” *Id* at 4. The Examiner maintains that the specification does not sufficiently describe the point of reference for asparagine 803. *See id.* at 4-5.

In light of the present amendment, the above rejection is moot. Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112, First Paragraph

Written description of FIH

The Examiner rejects claims 1, 3-6 and 29-33 under 35 U.S.C. § 112, First Paragraph, as “failing to comply with the written description requirement.” Final Office Action at 5. The Examiner alleges a “lack of correlation between structure and function for claimed genus method so that one skilled in the art would be able to possess the full scope of claimed method.” *Id.* at 6. The Examiner contends that “[t]he recited FIH is not defined by the instant specification; thus the instant FIH has been interpreted as any factor that inhibit[s] any protein or enzymes

belonging to the same family as the HIF.” *Id.* The Examiner then points to page 2 of the specification to reason that “instant FIH encompasses any protein, enzyme or polypeptide that inhibits enzymes belonging to the same family as HIF i.e. utilizing dioxygen (a cosubstrate), 2-oxoglutarate (2 OG) (a cosubstrate) and Fe(II) (a cofactor).” *Id.* The Examiner concludes, “[t]he claimed method of using a genus of FIH structure described above cannot be adequately described by the disclosure of species of the structure coordinates in the Table 3.” *Id.* at 7. The Examiner further contends that “[t]he recitation of homologues thereof is even broader than FIH according to the recited definition in the specification.” *Id.*

The present amendment renders the above rejection moot. Applicants respectfully request that this rejection be withdrawn.

Scope of enablement

The Examiner rejected claims 1, 3-6 and 29-33 under 35 U.S.C. § 112, first paragraph, scope of enablement. The Examiner alleges that:

the specification, while being enabling for a method comprising using the structural coordinates of 1H2K, 1H2L, 1H2M and 1H2N (see Table 3) for a method of identifying, screening, characterizing or designing a chemical entity which binds to human Factor Inhibiting Hypoxia Inducible Factor (FIH, SEQ NO: undisclosed) identified as Q969Q7 (NCBI database), does not reasonably provide enablement for a method comprising using any structural model of any protein, enzyme, or polypeptide that inhibits enzymes belonging to the same family as the HIF including a[n] X-ray diffraction measurements of a genus crystal comprising said FIH related protein.

Final Office Action at 8.

In light of the present amendment, the above rejection is also moot. Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 1, 3, 5, 6, 29, and 31-33 under 35 U.S.C. § 102(b) as allegedly being anticipated by Hewitson et al. (May 31, 2002, *The Journal of Biological Chemistry*, vol. 149, pages 26351-55). The Examiner interprets the instant FIH as including “any 2OG oxygenases identified on the basis of sequence analysis . . . encompassed by a very broad FIH.” Final Office Action at 12. The Examiner alleges that Hewtison teaches “a method comprising comparing a structural model of phosphomannose isomerase (PMI) complexed with zinc” as meeting the recited limitation of “structural model of FIH derived from structural factors or coordinates determined by X-ray diffraction” in Claims 1 and 29.” *Id.* Next the Examiner alleges that the binding of Zn in the protein crystal structure of Hewitson meets the limitations of claims 4 and 31. *See id.* Finally, the Examiner points to Hewitson’s disclosure of zinc inhibition of FIH, in view of an assay with GST-HIF-1 α as a substrates, and concludes that the methods of Hewitson anticipate claims 5-6 and 32-33. *See id.* at 12-13. Applicants respectfully disagree and traverse this ground of rejection.

A rejection under § 102 is proper only when the claimed subject matter is *identically described or disclosed* in the prior art. *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972) (emphasis added). Hewitson does not disclose all of the elements of the instant claims as presently amended. In particular, Hewitson does not disclose any crystal structure obtained from the FIH of the instant claims or any structural coordinates obtained therefrom. Therefore, Applicants respectfully contend that each of the claims is novel in view of the cited reference and respectfully request that the Examiner reconsider and withdraw the rejection of these claims under § 102.

Rejection under 35 U.S.C. § 103

The Examiner rejects claims 3 and 30 under 35 U.S.C. § 103 as being unpatentable over Hewitson et al. in view of *In re Gulack* 703 F.2d 1381, 217 U.S.P.Q. 401 (Fed. Cir. 1983) and *In re Ngai* 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

As an initial matter, claims 3 and 30 have been canceled. Moreover, Hewitson also does not teach an assay as recited in the presently amended independent claims. Therefore, Applicants respectfully submit that this rejection is also moot.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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